



PATENT
Customer No. 22,852
Attorney Docket No. 08702.0020-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of: |) | |
| |) | |
| VELDMAN et al. |) | Group Art Unit: 1645 |
| |) | |
| Application No.: 10/688,925 |) | Examiner: Not Yet Assigned |
| |) | |
| Filed: October 21, 2003 |) | |
| |) | |
| For: NEUTRALIZING ANTIBODIES |) | |
| AGAINST GDF-8 AND USES |) | |
| THEREFOR |) | |

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to 37 C.F.R. §§ 1.56 and 1.97(b), Applicants bring to the attention of the Examiner the documents listed on the attached PTO 1449. This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-referenced application.

Copies of the listed documents are attached.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached form.

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the

documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

If there is any fee due in connection with the filing of this Statement, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: March 24, 2004

By: Mary K. Ferguson
Mary K. Ferguson
Reg. No. 51,675



INFORMATION DISCLOSURE CITATION

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|-----------------------|------------------|------------|------------|
| Attorney's Office No. | 08702.0020-00000 | Appln. No. | 10/688,925 |
| Applicant | VELDMAN et al. | | |
| Filing Date | October 21, 2003 | Group: | 1645 |

U.S. PATENT DOCUMENTS

| Examiner Initial* | Document Number | Issue Date | Name | Class | Sub Class | Filing Date If Appropriate |
|-------------------|-----------------|------------|---------------|-------|-----------|----------------------------|
| | 5,639,638 | 06/17/1997 | Wozney et al. | 435 | 69.4 | 05/20/1994 |
| | 6,437,111 B1 | 08/20/2002 | Wozney et al. | 536 | 23.4 | 08/28/1997 |

FOREIGN PATENT DOCUMENTS

| Document Number | Publication Date | Country | Class | Sub Class | Translation Yes or No |
|-----------------|------------------|---------|-------|-----------|-----------------------|
| WO 00/43781 | 07/27/2000 | PCT | G01N | 33/50 | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| |
|--|
| Alexander et al., "Human Parathyroid Hormone 1-34 Reverses Bone Loss In Ovariectomized Mice", <i>J. Bone Min. Res.</i> 16:1665-1673 (2001) |
| Andersson et al., "Repeated <i>In Vivo</i> Determinations of Bone Mineral Density During Parathyroid Hormone Treatment in Ovariectomized Mice", <i>J. Endocrinol.</i> 170:529-537 (2001) |
| Ashmore et al., "Comparative Aspects of Muscle Fiber Types in Fetuses of the Normal and 'Double-Musclled' Cattle", <i>Growth</i> 38:501-506 (1974) |
| Bogdanovich et al., "Functional Improvement of Dystrophic Muscle by Myostatin Blockade", <i>Nature</i> 420:418-421 (2002) |
| Brown et al., "Physicochemical Activation of Recombinant Latent Transforming Growth Factor-beta's 1,2, and 3", <i>Growth Factors</i> 3:35-43 (1990) |
| Derynck et al., "Human Transforming Growth Factor- β Complementary DNA Sequence and Expression in Normal and Transformed Cells", <i>Nature</i> 316:701-705 (1985) |
| Gamer et al., "A Novel BMP Expressed in Developing Mouse Limb, Spinal Cord, and Tail Bud Is a Potent Mesoderm Inducer in <i>Xenopus</i> Embryos", <i>Dev. Biol.</i> 208:222-232 (1999) |
| Gentry et al., "The Pro Domain of Pre-Pro-Transforming Growth Factor β 1 When Independently Expressed Is a Functional Binding Protein for the Mature Growth Factor", <i>Biochemistry</i> 29:6851:6857 (1990) |
| Gonzalez-Cadavid et al., "Organization of the Human Myostatin Gene and Expression in Healthy Men and HIV-Infected Men With Muscle Wasting", <i>PNAS</i> 95:14938-14943 (1998) |
| Hamrick et al., "Femoral Morphology and Cross-Sectional Geometry of Adult Myostatin-Deficient Mice", <i>Bone</i> 27:343-349 (2000) |
| Hill et al., "The Myostatin Propeptide and the Follistatin-Related Gene Are Inhibitory Binding Proteins of Myostatin in Normal Serum", <i>J. Biol. Chem.</i> 277:40735-40741 (2002) |
| Hoodless et al., "Mechanisms and Function of Signaling by the TGF β Superfamily", <i>Current Topics in Microbiology and Immunology</i> pp. 236-272 (1998) |



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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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|--|---|
| | Kambadur et al., "Mutations in <i>Myostatin</i> (GDF8) In Double-Muscled Belgian Blue and Piedmontese Cattle", <i>Genome Res.</i> 7:910-915 (1997) |
| | Kim et al., "Inhibition of Preadipocyte Differentiation by Myostatin Treatment in 3T3-L1 Cultures", <i>Biochem. Biophys. Res. Comm.</i> , 281:902-906 (2001) |
| | Kingsley, D.M., "The TGF- β Superfamily: New Members, New Receptors, and New Genetic Tests of Function in Different Organisms", <i>Genes & Devel.</i> 8:133-146 (1994) |
| | Lee et al., "Regulation of Myostatin Activity and Muscle Growth", <i>PNAS</i> 98:9306-9311 (2001) |
| | Massagué, J., "The Transforming Growth Factor- β Family", <i>Ann. Rev. Cell Biol.</i> 6:597-641 (1990) |
| | McPherron et al., "Suppression of Body Fat Accumulation in Myostatin-Deficient Mice", <i>J. Clin. Invest.</i> 109:595-601 (2002) |
| | McPherron et al., "Regulation of Skeletal Muscle Mass in Mice by a New TGF- β Superfamily Member", <i>Nature</i> 387:83-90 (1997) |
| | McPherron et al., "Double Muscling in Cattle Due to Mutations in the Myostatin Gene", <i>PNAS</i> 94:12457-12461 (1997) |
| | Miyazono et al., "Latent High Molecular Weight Complex of Transforming Growth Factor β 1", <i>J. Biol. Chem.</i> 263:6407-6415 (1988) |
| | Nakashima et al., "Expression of Growth/Differentiation Factor 11, A New Member of the BMP/TGF β Superfamily During Mouse Embryogenesis", <i>Mech. Dev.</i> 80:185-189 (1999) |
| | Swatland et al., "Fetal Development of the Double Muscled Condition in Cattle", <i>J. Animal Sci.</i> 38:752-757 (1974) |
| | Thies et al., "GDF-8 Propeptide Binds to GDF-8 and Antagonizes Biological Activity by Inhibiting GDF-8 Receptor Binding", <i>Growth Factors</i> 18:251-259 (2001) |
| | Wagner et al., "Loss of Myostatin Attenuates Severity of Muscular Dystrophy in <i>mdx</i> Mice", <i>Ann. Neurol.</i> 52:832-836 (2002) |
| | Wakefield et al., "Latent Transforming Growth Factor- β From Human Platelets", <i>J. Biol. Chem.</i> 263:7646-7654 (1988) |
| | Whittemore et al., "Inhibition of Myostatin in Adult Mice Increases Skeletal Muscle Mass and Strength", <i>Biochem. Biophys. Res. Comm.</i> 300:965-971 (2003) |
| | Zimmers et al., "Induction of Cachexia in Mice by Systematically Administered Myostatin", <i>Science</i> 296:1486-1488 (2002) |

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|----------|-----------------|
| Examiner | Date Considered |
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.